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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639
20792 7590 06/16/2010 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/889,645

Applicant(s)

WELCH ET AL.

Examiner

AGNIESZKA BOESEN

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-10,12-16,25,28 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-10,12-16,25,28 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-85/86)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The Amendment filed March 8, 2010 in response to the Office Action of October 9, 2009 is acknowledged and has been entered. New claims 38 and 39 have been added. Claims 1, 3, 6-10, 12-16, 25, 28, and 31-39 are pending and under examination in this Office action.

Claim Rejections - 35 USC § 112

Rejection of Claims 1, 3, 6-10, 12-16, 25, 28 and 31-37 under 35 U.S.C. 112, first paragraph, **is withdrawn** in view of Applicant's arguments.

Claim Rejections - 35 USC § 103

Rejection of claims 1, 3, 6-10, 12-16, 25, 28 and 31-37 under 35 U.S.C. 103(a) as being unpatentable over Ostreicher et al. (GB 2 045 828 A, 1980) in view of Nebe (WO 96/05846, IDS Paper No. 1) as evidenced by Encyclopedia Britannica (britannica.com/eb/article-9030299/diatomaceous-earth, access 10/5/2006) **is withdraw** in view of Applicant's arguments.

It is noted that Applicant does not expressly argue that the cited references do not teach the **depth** filter. However the rejection is withdrawn because neither Ostreicher nor Nebe teach the **depth** filter.

New Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6-10, 12-16, 25, 28 and 31-39 under 35 U.S.C. 103(a) as being unpatentable over Morgenhalter et al. (US Patent 6,407,212 B1) in view of Breitenbach et al. (US Patent 6,083,408).

Morgenhalter teaches methods of removing prions from plasma products comprising passing the blood plasma product through the filter formed of a cellulose binder and kieselguhr or perlite particles, wherein the blood plasma product is albumin, immunoglobulins, fibrinogen and coagulation factors (see claims 1-18, columns 3 and 4 and Examples 1-6). Morgenhalter teaches the pH of 5.1, 5.8 and 5.95 and treating the filter with ethanol (see examples 1-3). Morgenhalter's method is carried out in the absence of the cationic charged material. Morgenhalter teaches a liquid subject to the prion removal such as human blood plasma (see Example 1). Morgenhalter teaches that the human blood plasma may contain a hormone (see column 3, lines 10-20).

Morgenhalter does not expressly teach depth filter, the specific pore size or the filter thickness or the filter permeability of 110 to 220 L/m²/min. Morgenhalter does not expressly teach the single use filter.

Breitenbach teaches methods of removing pathogenic microorganisms such as viruses from plasma products comprising passing the blood plasma product through the depth filter formed of a cellulose binder and kieselguhr or perlite particles having the size ranging from 0.5 to 300 μm (see claims 1-11, column 2, lines 15-30 and Examples 1 and 2).

Breitenbach's filter pore size ranging from 0.5 to 300 μm falls within the claimed pore size of less than 6 μm . It would have been obvious to optimize the filter pore size, the filter

thickness and the filter permeability. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

It is noted that while Morgenhalter does not expressly call his filter a depth filter, it is the position of the Office that Morgenhalter's filter is a depth filter since it is composed of identical components, (kieselguhr, perlite and cellulose) and it is used for the same purpose, removing submicron contaminants from human blood plasma as the depth filter disclosed in Breitenbach.

However, it would have been *prima facie* obvious to provide the Breitenbach's filter in the method of Morgenhalter because Breitenbach teaches that his filter can successfully pass human blood plasma products while removing contaminants such as viruses (claims 1-11, column 2, lines 15-30 and Examples 1 and 2).

It would have been obvious to provide a single use filter so that any contaminants are not transferred from one plasma product to another.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective

functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 14 is drawn to a liquid subjected to prion removal, wherein the liquid is human blood plasma. The human blood plasma does not define over the human blood plasma found in nature. Thus because the liquid claimed in claim 14 reads on the product of nature such as human blood plasma, the claimed invention is directed to non-statutory subject matter.

Double Patenting Warning

Applicant is advised that should claim 1 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

No claims are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/
Examiner, Art Unit 1648